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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,438	02/11/1999	MURRAY C. MAYTOM	PC10015AJTJ	8766

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GREGG C BENSON
PFIZER INC
PATENT DEPARTMENT BOX 519
EASTERN POINT ROAD
GORTON, CT 06340

EXAMINER
WANG, SHENGJUN

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/248,438	Applicant(s) MAYTOM ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted October 29, 2002 is acknowledged.

Double Patenting Rejection

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 2, 5-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-36 of copending Application No. 08/549,792, in view of Beretta et al. (Medline Abstract, AN 94136073) and Chancellor et al. (Medline Abstract, AN 94182317).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the U.S. application Serial No. 08/549,792, similar to the instant claims, are drawn to methods of treating sexual dysfunction broadly and male erectile dysfunction.

U.S. application Serial No. 08/549,792 does not expressly claim the treated subject is with injured spinal cord.

3. However, Berretta et al. and Chancellor et al. teach that vasoactive compounds are known to be useful for treatment of erectile dysfunction in men with injured spinal cord. See the abstracts.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury, including those who exhibits essentially no residual erectile function.

4. A person of ordinary skill in the art would have been motivated to employ the vasoactive, compounds herein for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function because the general established mechanism of sildenafil indicates it will be useful for treatment of ED in men with proper corpus cavernorsum tissue, including those with injured spinal cord. A person of ordinary skill in the art would have been motivated to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury because vasoactive compounds useful for treating erectile dysfunction are known to be useful for treating erectile dysfunction caused by spinal cord injury. Finally, an agent known to be useful for treating erectile dysfunction caused by spinal cord injury in men would have reasonably expected to be useful for treating erectile dysfunction caused by spinal cord injury in any men, including those who exhibit essentially no residue erectile function.

5. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejection 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/28902 (of record) in view of Beretta et al. (Medline Abstract, AN 94136073) and Chancellor et al. (Medline Abstract, AN 94182317).

WO 94/28902 teaches that the compounds of the claims are vasoactive compounds, known to be useful in the treatment of male erectile, sexual dysfunction. See, e.g., the abstract, page 2, and the claims. More specifically, sildenafil selectively inhibits PDEv enzyme and lead to an elevation of cGMP levels in corpus cavernorsum tissue. The elevation of cGMP levels in corpus cavernorsum tissue cause the tissue relaxation and consequent penile erection. See, page 9, the last paragraph bridging to page 10 in WO 94/28902.

8. WO 94/28902 does not teach expressly the employment of the treatment for man with injured spinal cord.

9. However, Berretta et al. and Chancellor et al. teach that vasoactive compounds are known to be useful for treatment of erectile dysfunction in men with injured spinal cord. See the abstracts.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the vasoactive compounds herein for

the treatment of ED in men with spinal cord injury, including those who exhibits essentially no residual erectile function.

10. A person of ordinary skill in the art would have been motivated to employ the vasoactive, compounds herein for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function because the general established mechanism of sildenafil indicates it will be useful for treatment of ED in men with proper corpus cavernorsum tissue, including those with injured spinal cord. A person of ordinary skill in the art would have been motivated to employ the vasoactive compounds herein for the treatment of ED in men with spinal cord injury because vasoactive compounds useful for treating erectile dysfunction are known to be useful for treating erectile dysfunction caused by spinal cord injury. Finally, an agent known to be useful for treating erectile dysfunction caused by spinal cord injury in men would have reasonably expected to be useful for treating erectile dysfunction caused by spinal cord injury in any men, including those who exhibit essentially no residue erectile function.

Response to the Arguments

Applicants' amendments and remarks submitted October 29, 2002 have been fully considered, but are not persuasive regarding the rejection above for reasons discussed below.

1. Initially, it is noted that the claims in WO 94/28902 or Application No. 08/549,792 are generic to claim herein. Particularly, the references teach a method for treating male erectile dysfunction generally. There is no limitation as to the particular under etiology of the dysfunction. The second references particularly teach that treating erectile dysfunction caused by spinal injury is similarly as treating erectile dysfunction in general, e.g., employing vasoactive compounds. It is well-settled fact that in treating syndromes, therapy is directed to alleviating

symptomology. That eliminating the underlying etiology results in disease suppression is well known to the skilled artisan. Similarly, faced with a disease state, the skilled artisan would have been motivated to treat these symptoms with medicaments old and well known to treat the disease state; regardless the underlying etiology. Thus regardless the etiology, to treat erectile dysfunction with old and well-known PDE V inhibitor would have been obvious to the normal skilled artisan. Therefore, the argument that the second references do not teach the particular compounds herein for treating erectile dysfunction caused by spinal cord injury is not persuasive. Applicants fails to provide objective evidence showing why a known method for treating erectile dysfunction is not obvious for treating erectile dysfunction caused by spinal cord injury, particularly in view the fact that the known method employs a vasoactive agent, and vasoactive agents are known to be useful for treating erectile dysfunction caused by spinal cord injury.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

Shengjun Wang

January 2, 2003